RESEARCH SUBJECT PROTECTION PROGRAM
NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES

www.state.nj.us/health/rspp

IRB SUBMISSION CHECKLIST

Make the appropriate number of copies of the following documents *[Full Board review: 25 copies; Expedited Review: 3 copies; and Exempt Review: 2 copies. If you are requesting a Full Board Review only include 3 copies of the budget and grant application or contract, if applicable.]*

- ☐ IRB Application
- ☐ Protocol
- ☐ Agreement for the Responsible Conduct of Research
- ☐ Agreement for the Protection of Research Subjects
- ☐ Institutional Approval of Intramural Research *(for DHSS employees)*
- ☐ Institutional Approval of Extramural Research *(for non-DHSS employees)*
- ☐ Informed Consent Documents (forms, scripts, etc.)
- ☐ Instruments (survey, questionnaire, abstraction form, rating scale, etc.)
- ☐ CITI course certificates for all Investigators and Support Personnel
- ☐ Curriculum Vitae for all investigators and key support personnel (five page maximum)
- ☐ Grant Application or Contract
- ☐ Budget *(If applicable)*
- ☐ Letter of Indemnification *(If applicable)*
- ☐ Investigator Agreement *(If applicable)*
- ☐ Confidentiality Agreement *(If applicable)*
- ☐ Sponsor Protocol *(If applicable)*
- ☐ For FDA-regulated research, Form 1572
- ☐ For FDA-regulated research, Investigator Brochure
- ☐ For FDA-regulated research, Package Insert
- ☐ For FDA-regulated research, Clinical Trial Agreement
- ☐ For FDA-regulated research on non-significant risk devices, the sponsor's risk assessment report, and if the device has been reviewed by the FDA, the FDA's risk assessment report.

I hereby certify that the above-checked documents have been included with the appropriate number of copies.

Name of Principal Investigator (Print)	
Signature	Date